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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,112	MORI ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-37,39,40 and 46-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-37,39,40 and 46-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/31/2006, 7/20/2006, 1/3/2007, 3/4/2009, 7/1/2009 and 8/3/2009.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 3/31/2006, in which claims 1-23, 38, and 41-45 were canceled, and claims 26, 30-32, 37, 39, 40, 50, 55, 57-59, 62 and 64 were amended. Receipt is also acknowledged of an amendment, filed 7/1/2009, in which the status identifiers of some of the claims were updated.

It is noted that amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having

the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

The amendments to the claims filed on 3/31/2006 and 7/1/2009 have been entered. However, proper status identifiers for the claims have not been provided. In the amendment filed 7/1/2009, claims 24, 25, 27-29, 33-36, 46-49, 51-54, 56, 60, 61 and 63 should have the status identifier "original," and claims 26, 30-32, 37, 39, 40, 50, 55, 57-59, 62 and 64 should have the status identifier "previously presented." In response to this Office action, Applicant must provide a claim listing in compliance with 37 CFR 1.121(c).

Currently, claims 24-37, 39, 40 and 46-64 are pending and under consideration.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt of the certified copies of the foreign priority documents, Japan 2003-343747, Japan 2003-350091, and Japan 2004-056912, is acknowledged. These papers have been placed of record in the file.

Information Disclosure Statement

Receipt of information disclosure statements, filed on 3/31/2006, 7/20/2006, 1/3/2007, 3/4/2009, 7/1/2009 and 8/3/2009, is acknowledged. The signed and initialed PTO 1449s have been mailed with this action.

Sequence Compliance

This application is objected to because it does not include the statement that the sequence listing information recorded in computer readable form (CRF) and the written (on paper or compact disc) sequence listing includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). Correction is required.

The CRF and written sequence listing were filed on 7/1/2009. However, the statement of no new matter was not provided.

Specification

The disclosure is objected to because of the following informalities: the paragraph at lines 8-22 of page 45 should indicate that the G-box motif (GCCACGTGCC) is SEQ ID NO: 5, rather than indicating that the PG10-90 promoter is SEQ ID NO: 5.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 28.

The use of the trademark CDP-STAR (pages 59 and 69) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-29, 31, 32, 37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasochova et al (US Patent Application Publication No. 2003/0074677 A1; see the entire reference).

Regarding claim 24, Rasochova et al teach a DNA molecule comprising cDNA of an RNA virus vector that has been constructed by inserting an exogenous RNA component and a ribozyme sequence at the 3' region (e.g., paragraph [0049]). Rasochova et al teach the DNA molecule where the exogenous RNA component has a coding function in which the RNA acts as a messenger RNA, encoding a sequence which, when translated by the host cell, results in the synthesis of a peptide or protein (e.g., paragraph [0047]).

Regarding claims 25-29, Rasochova et al teach the DNA molecule where the virus vector originates in a virus that is a single strand (+) RNA virus, such as barley stripe mosaic virus or tobacco mosaic virus (e.g., paragraphs [0042], [0135], [0139] and [0141]).

Regarding claim 31, Rasochova et al teach the DNA molecule where the exogenous RNA component is inserted in place of the coat protein coding sequence (e.g., paragraphs [0057] and [0137]).

Regarding claim 32, Rasochova et al teach the DNA molecule, where the promoter that directs the expression of the exogenous RNA and ribozyme is an inducible promoter (e.g., paragraphs [0049]-[0050]).

Regarding claim 37, Rasochova et al teach a vector that comprises the DNA molecule and is capable of being incorporated into a cellular genome (e.g., paragraphs [0008]-[0010] and [0044]).

Regarding claim 39, a kit is a collection of items. Rasochova et al teach a DNA fragment and vector comprising cDNA of an RNA virus vector that has been constructed by inserting an exogenous RNA component and a ribozyme sequence at the 3' region (e.g., paragraph [0049]). Rasochova et al teach the DNA molecule where the exogenous RNA component has a coding function in which the RNA acts as a messenger RNA, encoding a sequence which, when translated by the host cell, results in the synthesis of a peptide or protein (e.g., paragraph [0047]). Thus, Rasochova et al teach the claimed kit.

Regarding claim 40, Rasochova et al teach a transformant obtained by transfection of a plant cell with a vector comprising a DNA fragment comprising cDNA of an RNA virus vector that has been constructed by inserting an exogenous RNA component and a ribozyme sequence

at the 3' region (e.g., paragraphs [0009], [0010], [0049], [0054] and [0058]). Rasochova et al teach the DNA molecule where the exogenous RNA component has a coding function in which the RNA acts as a messenger RNA, encoding a sequence which, when translated by the host cell, results in the synthesis of a peptide or protein (e.g., paragraph [0047]).

Claims 24-26, 30, 31, 37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al (The Plant Journal, Vol. 27, No. 1, pages 79-86, 2001, cited on the IDS filed 3/31/2006; see the entire reference).

Regarding claim 24, Mori et al teach a DNA fragment comprising a cDNA of a Brome mosaic virus that has been constructed by inserting a coding sequence of a human gamma interferon (IFN) protein into the RNA virus, and ligating a ribozyme sequence to the 3' end of the virus vector cDNA (e.g., page 85, paragraph bridging columns; Figure 1).

Regarding claims 25 and 26, Mori et al teach the DNA fragment wherein the virus vector originates in a virus that is a Brome mosaic virus, which is a single strand (+) RNA plant virus (e.g., page 80, right column, 2nd full paragraph).

Regarding claim 30, Mori et al teach the DNA fragment where the ribozyme sequence is a ribozyme sequence of satellite tobacco ringspot virus (e.g., page 85, paragraph bridging columns).

Regarding claim 31, Mori et al teach the DNA fragment where the IFN sequence was inserted in place of the coat protein gene (e.g., page 80, right column, 2nd full paragraph).

Regarding claim 37, Mori et al teach a vector comprising the DNA fragment, where the vector is capable of being incorporated into a cellular genome (e.g., paragraph bridging pages 80-81).

Regarding claim 39, a kit is a collection of items. Mori et al teach a DNA fragment and a vector comprising a cDNA of a Brome mosaic virus that has been constructed by inserting a coding sequence of a human gamma interferon (IFN) protein into the RNA virus, and a ribozyme sequence ligated to the 3' end of the virus vector cDNA (e.g., page 85, paragraph bridging columns; Figure 1). Thus, Mori et al teach the kit of claim 39.

Regarding claim 40, Mori et al teach a transformant of *N. benthamiana*, which is obtained with a vector including a cDNA of a Brome mosaic virus that has been constructed by inserting a coding sequence of a human gamma interferon (IFN) protein into the RNA virus, and a ribozyme sequence ligated to the 3' end of the virus vector cDNA (e.g., page 85, paragraph bridging columns; Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (The Plant Journal, Vol. 27, No. 1, pages 79-86, 2001, cited on the IDS filed 3/31/2006; see the entire reference) in view of Zuo et al (US Patent No. 6,452,068 B1; see the entire reference).

The teachings of Mori et al are described above and applied as before.

Mori et al do not teach the DNA fragment further comprising a transcription factor for controlling transcription induced by an inducible promoter, where (i) the transcription factor is GVG and the inducible promoter is 6XUASgal4, or (ii) the transcription factor is XVE and the inducible promoter is O_{LexA}-46.

Zuo et al teach a single vector comprising a promoter operably linked to a transcription factor and a promoter regulated by the transcription factor operably linked to a protein coding gene (e.g., column 9, line 27 to column 11, line 2). Zuo et al teach the vector where the transcription factor is a chimeric transcription factor in which the regulatory region of the rat glucocorticoid receptor (GR) is added to the DNA-binding domain of the yeast transcription factor GAL4 and the transactivating domain of the herpes viral protein VP16, where the chimeric transcription factor is called GVG (e.g., column 9, lines 50-67). When the vector comprises the GVG transcription factor, the inducible promoter contains six copies of the GAL4 upstream activating sequence (UAS) (6xUASGal4, e.g., column 9, lines 50-67; Figure 1). Zuo et al teach another construct referred to as XVE, which is similar to the GVG system but contains the DNA

binding domain of the bacterial repressor LexA and the regulatory region of the human estrogen receptor (e.g., column 10, lines 43-53). Zuo et al specifically teach that the XVE construct can be used in place of the GVG construct as long as the proper inducer is used for the construct being used (e.g., column 10, lines 48-51). When the vector comprises the XVE transcription factor, the inducible promoter contains eight copies of LexA binding sites fused to the 35S minimal promoter at -46 (O_{LexA}-46; e.g., paragraph bridging columns 20-21; Figure 13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vector of Mori et al to include the GVG coding sequence and the IFN coding sequence on the same vector as taught by Zuo et al because Zuo et al teach it is within the ordinary skill in the art to use a single vector for expression of a transcription factor for regulating an inducible promoter and for expression of a protein operably linked to the inducible promoter when the GVG transcription factor and 6XUASgal4 promoter is contained in the vector. With regard to claim 36, it would have been obvious to further modify the single vector comprising the GVG coding sequence and 6XUASgal4 sequence to replace the GVG coding sequence with the XVE coding sequence and to replace the 6XUASgal4 promoter with the O_{LexA}-46 promoter, because Zuo et al specifically teach that the XVE system can be used in place of the GVG system as long as the appropriate inducer is used.

One would have been motivated to make such a modification in order to receive the expected benefit of reducing the transformation and crossing steps to bring the GVG coding sequence and IFN coding sequence into the same plant cell as taught by Mori et al (e.g., page 82, *Production of transgenic plants containing cDNA of RNA1 or cDNAs of both RNA2 and FCP2IFN*; pages 82-83, *Induced replication of FCP2IFN and subgenomic mRNA amplification*

in GVG1 x 2FR plants) to a single step based on the production of a single vector containing all necessary elements of the inducible system, as taught by Zuo et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 46-48, 50, 51 and 55-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (The Plant Journal, Vol. 27, No. 1, pages 79-86, 2001, cited on the IDS filed 3/31/2006; see the entire reference) in view of David et al (Plant Physiology, Vol. 125, pages 1548-1553, April 2001; see the entire reference).

Mori et al teach a process for producing a transformant for protein production, comprising (i) transforming *N. benthamiana* host cells with a GVG transcription factor-expressing DNA fragment in which the GVG coding sequence is operably linked to the CaMV 35S promoter; where transforming is done by an Agrobacterium method (ii) screening the transformants obtained in step (i) for an individual F0 plant expressing GVG; and (iii) crossing the F0 GVG-expressing plants with 2FR plants containing cDNA of a virus vector that has been constructed by inserting a coding gene of human gamma interferon (IFN) into an RNA virus, where the IFN coding sequence is ligated to the 6XUASGal4 inducible promoter, which is induced by the GVG transcription factor (e.g., page 82, *Production of transgenic plants containing cDNA of RNA1 or cDNAs of both RNA2 and FCP2IFN*; pages 82-83, *Induced replication of FCP2IFN and subgenomic mRNA amplification in GVG1 x 2FR plants*; page 85, *Transformation of Nicotiana benthamiana*; Figure 1). Specifically, the virus vector used in the

method of Mori et al contains a cDNA of a Brome mosaic virus that has been constructed by inserting a coding sequence of a human gamma interferon (IFN) protein into the RNA virus, and ligating a ribozyme sequence to the 3' end of the virus vector cDNA (e.g., page 85, paragraph bridging columns; Figure 1). The ribozyme sequence is a ribozyme sequence of satellite tobacco ringspot virus (e.g., page 85, paragraph bridging columns). In the virus vector, the IFN sequence was inserted in place of the coat protein gene (e.g., page 80, right column, 2nd full paragraph). Further, Mori et al teach a transformant produced by the abovementioned process, where the transformant produces IFN protein in the presence of dexamethasone (e.g., Figure 4). Mori et al teach that the GVG transcription factor has a property of being activated by the hormone dexamethasone, a synthetic steroid hormone (e.g., page 82, *Analysis of the accumulation of RNA1 in response to DEX treatment*). Mori et al teach the method where the virus vector originates in a virus that is a Brome mosaic virus, which is a single strand (+) RNA plant virus (e.g., page 80, right column, 2nd full paragraph). With regard to claim 64, a kit is a collection of items, and Mori et al teach at least one item for use in the process of producing the abovementioned transformant (e.g., page 85, Experimental procedures).

Mori et al do not teach the method where the GVG transformants are further transformed with the cDNA of a virus vector that encodes IFN using an Agrobacterium method. Further, Mori et al do not teach the method where the cells are tobacco BY-2 cells.

David et al teach that the tobacco (*Nicotiana tabacum*) BY2 cell line is well characterized, highly homogenous, and shows an exceptionally high growth rate (e.g., page 1548, left column, 1st paragraph). Further, David et al teach that BY2 cells can be easily transformed without the need for protoplast preparation and stable transgenic calli, and

suspension-cultured cells are easily obtained (e.g., page 1548, left column, 1st paragraph). David et al teach a method that brings together the advantages of the BY2 cell line with the advantages of the tetracycline derepressible system (e.g., page 1548, right column, full paragraph). David et al teach a method for producing a transformant for protein production, comprising (i) transforming BY2 cells with pBinTet1 vector, containing tetR under the control of the cauliflower mosaic virus (CaMV)-35S promoter; (ii) selecting clonal and stable transformants, named BY2-tetR, on kanamycin medium; (iii) and transforming the BY2-tetR cells with a pTX-Gus-int, a vector containing β-glucuronidase (Gus) under the control of the "Triple-Op" promoter coupled with CaMV 35S (e.g., paragraph bridging pages 1548-1549; page 1549, left column). David et al teach that Gus activity was induced in the BY2-tetR cells comprising pTX-Gus-int by the addition of AhTc (e.g., Figure 1). David et al teach that a high steady-state expression of tetR ensures an efficient repression of the "Triple-Op" promoter (e.g., paragraph bridging pages 1549-1550). David et al teach Agrobacterium-mediated transformation of the BY2 cells (e.g., page 1552, Cell Transformation).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Mori et al to include a first Agrobacterium-mediated transformation step of BY2 cells with the GVG expression vector, and a second Agrobacterium-mediated transformation step of BY2 cells with the IFN expression vector, as taught by David et al because David et al teach it is within the ordinary skill in the art to use BY2 cells for regulated expression of a protein product and Mori et al teach regulated expression of the IFN protein product.

One would have been motivated to make such a modification in order to receive the expected benefit of selecting for BY2 GVG transformants with desirable levels of GVG expression prior to transformation with the IFN expression vector, because David et al teach that desirable levels of tetR could be identified prior to the second transformation step. It would have been within the ordinary skill of the art to transform the BY2 cells based upon the teachings of David et al, and it would have been within the skill of the art to screen for desirable levels of GVG by Northern blotting as taught by Mori et al. Furthermore, one would have been motivated to perform a second transformation step in BY2 cells rather than produce plants and cross the plants as taught by Mori et al in order to save time, because David et al teach that BY2 cells have an exceptionally high growth rate and are easy to transform. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (The Plant Journal, Vol. 27, No. 1, pages 79-86, 2001, cited on the IDS filed 3/31/2006; see the entire reference) in view of David et al (Plant Physiology, Vol. 125, pages 1548-1553, April 2001; see the entire reference) as applied to claims 46-48, 50, 51 and 55-64 above, and further in view of Zuo et al (US Patent No. 6,452,068 B1; see the entire reference).

The combined teachings of Mori et al and David et al are described above and applied as before.

Mori et al and David et al do not teach the method where the transcription factor is LexA-VP16-hER, the inducible promoter is O_{LexA}-46, and the inducer is estrogen.

Zuo et al teach the vector where the transcription factor is a chimeric transcription factor in which the regulatory region lf the rat GR is added to the DNA-binding domain of the yeast transcription factor GAL4 and the transactivating domain of the herpes viral protein VP16, where the chimeric transcription factor is called GVG (e.g., column 9, lines 50-67). When the vector comprises the GVG transcription factor, the inducible promoter contains six copies of the GAL4 upstream activating sequence (UAS) (6xUASGal4, e.g., column 9, lines 50-67; Figure 1). Zuo et al teach another construct referred to as XVE, which is similar to the GVG system but contains the DNA binding domain of the bacterial repressor LexA and the regulatory region of the human estrogen receptor (e.g., column 10, lines 43-53). Zuo et al specifically teach that the XVE construct can be used in place of the GVG construct as long as the proper inducer is used for the construct being used (e.g., column 10, lines 48-51). When the vector comprises the XVE transcription factor, the inducible promoter contains eight copies of LexA binding sites fused to the 35S minimal promoter at -46 (O_{LexA}-46), and the inducer is estrogen (e.g., Example 12; Figure 13).

Mori et al and David et al both teach the use of regulatable transcription factors capable of being modulated for regulated expression of a protein. Mori et al specifically teaches the use of the GVG system, and Zuo et al specifically teaches that it was within the skill of the art to substitute the XVE system for the GVG system in order to achieve the predictable result of providing inducible expression of a protein. The XVE system comprises the claimed LexA-VP16-hER transcription factor, which is activated by estrogen, and the O_{LexA}-46 promoter.

Claims 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al (The Plant Journal, Vol. 27, No. 1, pages 79-86, 2001, cited on the IDS filed 3/31/2006; see the entire reference) in view of David et al (Plant Physiology, Vol. 125, pages 1548-1553, April 2001; see the entire reference) as applied to claims 46-48, 50, 51 and 55-64 above, and further in view of Rasochova et al (US Patent Application Publication No. 2003/0074677 A1; see the entire reference).

The combined teachings of Mori et al and David et al are described above and applied as before.

Mori et al and David et al do not teach the method where the virus vector comprises tobacco mosaic virus.

Rasochova et al teach a vector comprising cDNA of an RNA virus vector that has been constructed by inserting an exogenous RNA component and a ribozyme sequence at the 3' region (e.g., paragraph [0049]). Rasochova et al teach the vector where the exogenous RNA component has a coding function in which the RNA acts as a messenger RNA, encoding a sequence which, when translated by the host cell, results in the synthesis of a peptide or protein (e.g., paragraph [0047]). Rasochova et al teach the vector where the virus vector originates in a virus that is a single strand (+) RNA virus, such as tobacco mosaic virus (e.g., paragraphs [0042], [0135], [0139] and [0141]). Rasochova et al teach the DNA molecule where the exogenous RNA component is inserted in place of the coat protein coding sequence (e.g., paragraphs [0057] and [0137]). Rasochova et al teach the use of the vector to make transgenic plants expressing the protein (e.g., paragraphs [0138]-[0141]). Further, Rasochova et al teach it is within the skill of

the art to use an inducible promoter for the expression of the exogenous RNA component (e.g., paragraphs [0049]-[0050]).

Because Mori et al and Rasochova et al both teach vectors for the expression of a protein in plant cells, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the tobacco mosaic virus vector of Rasochova et al for the Brome mosaic virus vector of Mori et al, where expression of the protein is under the control of the 6xUASgal4 promoter, in order to achieve the predictable result of providing a vector for the inducible expression of a protein in a plant cell.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Jennifer Dunston/
Examiner
Art Unit 1636